REPORT TO CONGRESS

MEDICARE INFLUENZA VACCINE DEMONSTRATION

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Secretary of Health and Human Services
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EXECUTIVE SUMMARY

1.0 Introduction

The Omnibus Budget Reconciliation Act of 1987 mandated a demonstration and evaluation of a Medicare influenza vaccine benefit. The Secretary of Health and Human Services was authorized to spend $25 million each year to fund the demonstration, bulk-purchase and distribute influenza vaccine, and evaluate the demonstration. If, after 2 years, data were insufficient to support conclusions on cost-effectiveness, the demonstration would continue for 2 additional years. The Department delivered an interim Report to Congress on October 15, 1990 that explained the need to continue the demonstration. Unless the final Report to Congress, due no later than April 1, 1993, were to conclude that a benefit would not be cost-effective, Medicare would then extend coverage for influenza vaccinations no later than 1 month from delivery of the report. The Department submits this report in fulfillment of the Congressional mandate.

2.0 Major Research and Design Issues

In this report, the Department presents measures of the costs and savings of a benefit to the Medicare program, which depend upon 1) the effect of Medicare coverage on elderly vaccination rates, with or without outreach to beneficiaries and providers (the "vaccination rate effect"); 2) the effectiveness of influenza vaccine at reducing hospital admissions and other Medicare-reimbursable services ("vaccine effectiveness"); and 3) the direct and indirect costs of a vaccination program.

The Department implemented a demonstration in 10 paired demonstration sites, each of which included an intervention area (to which the Department supplied bulk-purchased vaccine free to the provider and beneficiary) and a comparison area (without free vaccine). Later in the demonstration, in 10 additional statewide sites, carriers were instructed to pay reasonable charges for influenza vaccinations administered to Part B-eligible beneficiaries.

3.0 Implementing and Operating the Demonstration

Over the 4 years of the demonstration, the Department bulk-purchased influenza vaccine and distributed to the 10 paired demonstration sites from 200,000 doses (Year 1) to 1,328,400 doses (Year 4); carriers in the 10 statewide sites processed payments for providers for 500,000 doses (Year 2), 1.3 million doses (Year 3), and over 1.7 million doses (Year 4). Total Federal Government expenditures for the program increased from $6.2 million in Year 1 to $22.5 million in Year 4.

Demonstration funds supported the demonstration sites' outreach to providers and beneficiaries and an informational letter to all beneficiaries, tracking systems that monitored use of the vaccine and the occurrence of adverse medical events associated with

vaccinations, and surveillance systems that determined time periods within which influenza circulated during each year in each site. The demonstration proved to be successful, showing that the sites could quickly implement outreach and monitoring systems, that carriers could quickly implement a program closely resembling a Medicare vaccine benefit, and that a system for bulk purchase and distribution of vaccine by the Federal Government was feasible.

4.0 The Effects of Medicare Coverage on Beneficiary Vaccination Rates

Each year during the demonstration, beneficiaries and nursing homes in each of the paired demonstration sites and in four of the statewide sites were surveyed, to determine vaccination rates among community-dwelling and institutionalized elderly.

The community survey showed that vaccination rates increased by 22 percentage points (from 37 to 59 percent) in intervention areas, which were provided free vaccine. Rates also increased in comparison areas, which were not provided vaccine, by 11 percentage points (from 35 percent to 46 percent). Subtracting the comparison area increase from the increase in intervention areas, the Department concludes that the "vaccination rate effect" of coverage and some outreach to beneficiaries and providers should be about 11 percentage points. Among the statewide sites that did not conduct outreach programs, vaccination rates increased only 3 percentage points above increases in comparison area. The Department estimates this to be the vaccination rate effect of Medicare coverage without outreach.

The nursing home survey showed that roughly 70 percent of eligible beneficiaries in nursing homes are vaccinated each year and that the demonstration had no apparent impact on nursing home vaccination rates, which were the same in intervention and comparison areas.

5.0 Influenza Vaccine and Medicare-Reimbursable Health Services Utilization

A Medicare benefit could not generate savings at any vaccination rate unless the vaccine had a protective effect. The Department sponsored both epidemiological studies and analyses of Medicare claims to test the hypothesis that influenza vaccinations reduce hospital admissions and other health services utilization.

Epidemiological studies conducted in four States with paired demonstration sites produced estimates of influenza vaccine effectiveness in reducing the number of hospital admissions for pneumonia and influenza (P and I) from November through April of each year. These estimates ranged from zero to 35 percent reductions in relatively mild influenza years (estimated to occur in about 6 of every 10 years) and from zero to 52 percent in severe years (estimated to occur in about 4 of every 10 years). The most likely estimate is 33 percent reduction (95 percent confidence interval 11-49).

In contrast, analyses of claims for Medicare hospital admissions of vaccinated and unvaccinated beneficiaries did not detect any statistically significant effectiveness of the vaccine in reducing hospital or skilled nursing facility admissions. Analyses of area-level hospital admissions rates also found no evidence that the demonstration, by increasing vaccination rates, had any significant effect in reducing hospital admissions for P and I.

6.0 The Direct Costs of a Medicare Benefit

The Department estimated program costs for two models of a Medicare influenza vaccine benefit: 1) a traditional system of purchase and distribution, where carriers pay providers reasonable charges for the full purchase, distribution, and administration costs of vaccinations; and 2) a bulk-purchase system, in which the Federal Government buys and distributes the vaccine, and Medicare pays providers only to cover the administration costs. Costs were estimated with and without expenditures for outreach to beneficiaries and providers. It was assumed that Medicare would pay for vaccinating eligible nursing home residents as well as community-dwelling elderly.

Bulk-purchase generates the lowest cost per beneficiary. For example, assuming a vaccination rate effect of 10 percentage points and no outreach, bulk-purchase costs $1.65 per beneficiary ($4.13 per dose of vaccine), compared to $2.23 per beneficiary ($5.58 per dose) for the traditional system.

7.0 The Cost-Savings and Cost-Effectiveness of a Medicare Influenza Vaccine Benefit

The Department estimated annual average Medicare net costs (or savings) of an influenza vaccine benefit as the sum of vaccine program costs and savings in Parts A and B costs of P and I hospital admissions. A range of vaccination rates was used, from 35 through 60 percent, representing effects of Medicare coverage from 5 to 30 percentage points above the baseline rate, all consistent with values observed during the demonstration. Estimates of vaccine effectiveness (in reducing P and I hospital admissions) ranged from 5 to 70 percent, well within the ranges of values observed in the epidemiological studies conducted during the demonstration; vaccine was assumed to be half as effective in mild influenza years as in severe years. The Department used cost estimates for the traditional system, considered most likely to be implemented with a vaccine benefit.

These combined assumptions produce a range of estimated costs and savings for Medicare. For example, at a 40 percent vaccination rate, assuming that the vaccine is 40 percent effective in severe influenza years but only 20 percent effective in mild years, Medicare would incur added costs of $0.11 per beneficiary, or about $3.4 million. At the same vaccination rate and vaccine effectiveness rates of 42 and 21 percent, the program would be budget-neutral, neither costing nor saving money for Medicare. At higher

vaccine effectiveness rates, for example 50 and 25 percent, a Medicare vaccine benefit would generate net savings of $0.47 per beneficiary, or about $14.6 million.

The sensitivity of these findings was tested with alternative assumptions. Costs per beneficiary would decline, from $0.11 per beneficiary (under the basic assumptions used above) to $0.04 (if the vaccine were bulk purchased). If vaccine were totally ineffective in mild years, the chances that Medicare would incur added costs under an influenza vaccine benefit would increase.

The Department also estimated the expected costs per death averted and per year of life gained if a Medicare benefit were implemented. Assuming a 40 percent vaccination rate, and vaccine effectiveness rates of 40 and 20 percent, the costs per death averted would be $1,871, considerably lower than estimates computed for breast cancer screening ($123,000 to avert a single death). Costs per year of life gained would be $145, compared to estimates of nearly $1,000 per year of life for pneumococcal vaccine. Other potential benefits of influenza vaccination, including, for example, increased productivity (of beneficiaries and their potential caregivers), were noted but not explicitly addressed in the research.

The task of proving that an influenza vaccine benefit would not, under most reasonable circumstances, be cost-effective was not possible, given the wide ranges of estimates of critical measures, the highly variable nature of influenza, and the unexpectedly high baseline vaccination level.

The Department concludes that the cost-saving potential of a Medicare influenza vaccine benefit is ambiguous. Therefore, Medicare will initiate coverage for influenza vaccinations at the beginning of the first month after the date of this report. Based on analyses presented in this study, the Department believes that the new benefit could generate financial effects on Medicare within a wide range, from added annual costs or savings of $50 million. Within this range, based on the demonstration findings, which support a vaccination rate effect of about 10 percentage points and estimates of vaccine effectiveness of 30 percent in severe years and 15 percent in mild years, the evaluation contractor estimated added annual costs of about $20 million. HCFA's Office of the Actuary estimated projected costs as follows: $50 million in fiscal years (FY) 1994 and 1995; $45 million in FYs 1996 and 1997; and $40 million in FY 1998.

1.0 Introduction

In 1981, a study completed by the Office of Technology Assessment (OTA) concluded that influenza vaccinations were cost-effective for the elderly and suggested that Medicare might include vaccinations as a covered benefit. Six years later, the Omnibus Budget Reconciliation Act (OBRA) of 1987 mandated a demonstration and evaluation of the cost-effectiveness of a Medicare influenza vaccine benefit. The Secretary of Health and Human Services was authorized to spend $25 million each year to fund the demonstration, bulk-purchase and distribute influenza vaccine, and evaluate the demonstration. If, after 2 years, data were insufficient to support conclusions on cost-effectiveness, the demonstration would continue for 2 years. The Department delivered an interim Report to Congress on October 15, 1990 that explained the need to continue the demonstration. Unless the final Report to Congress, due no later than April 1, 1993, concluded that a benefit would not be cost-effective, Medicare would then extend coverage for influenza vaccinations no later than 1 month from delivery of the report.

The Health Care Financing Administration (HCFA), working with the Centers for Disease Control (CDC), implemented the demonstration, bulk-purchased vaccine for distribution to demonstration sites, and evaluated the demonstration. The Department submits this report in fulfillment of the Congressional mandate.

The elderly are considered to be at particularly high risk for influenza-associated illness, hospitalization, and death; some researchers estimate that influenza causes 10,000 to 40,000 deaths among the elderly each year (CDC, Prevention of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 1991). CDC's ACIP recommends influenza vaccinations for all persons 65 years of age and older, but until recently, barely 20 percent have received annual vaccinations. Uncertainty about the effectiveness of the vaccine for elderly persons has probably hampered efforts to increase vaccinations. Most studies of the effectiveness of influenza vaccine focus on nursing home populations. Until the Medicare demonstration, only a study published by

Barker and Mullooly (1986) reported estimates of vaccine effectiveness among elderly living in the community. During some years, Barker and Mullooly estimated the vaccine to be highly effective, reducing hospitalization rates by 72 percent. In other years, they found that the vaccine had no effect on hospitalizations. Changes in the type and severity of influenza from season to season partially explain this finding.

Over the 1980s and before the demonstration, influenza has varied widely in type and severity. Epidemic levels of Type A (H3N2), closely linked with excess morbidity and mortality among the elderly, occurred in 4 of the 10 years. During the demonstration, three influenza seasons were characterized by Type A influenza--1988-89, a relatively moderate season, and the particularly severe seasons of 1989-90, and 1991-92. Influenza during the third year of the demonstration was predominantly Type B and unusually mild.

2.0 Major Research and Design Issues

The Department designed a demonstration to deliver maximum amounts of vaccine to eligible beneficiaries and to address questions about the effects of Medicare coverage on vaccination rates and on health-related outcomes.

In this report, the Department presents measures of the costs and savings of a benefit to the Medicare program.[1] The net costs or savings of a Medicare influenza vaccine benefit depend upon:

1. the effect of Medicare coverage on elderly vaccination rates, with or without outreach to beneficiaries and providers (the "vaccination rate effect");

2. the effectiveness of influenza vaccine at reducing hospital admissions and other Medicare-reimbursable services ("vaccine effectiveness"); vaccine effectiveness depends mainly on factors other than Medicare coverage (i.e.,

[1]An expanded version of this report, including detailed results from all the studies conducted through the evaluation, will be available in October 1993.

the type and severity of influenza, the match of the vaccine to circulating influenza virus); and

3. the direct and indirect costs of a vaccination program.

Research questions included the following:

The Vaccination Rate Effect:

- Would the influenza vaccination rate among Medicare enrollees increase if Congress extended coverage under Medicare Part B?

- How do outreach and vaccine promotion to providers and beneficiaries, as distinct from Medicare payment, affect vaccination rates among eligible Medicare beneficiaries?

Vaccine Effectiveness

- How effective is influenza vaccine at reducing utilization of Medicare-reimbursable health services?

Medicare Costs of an Influenza Vaccine Program:

- What would be the direct and indirect costs to the Medicare program of an influenza vaccine benefit?

- How would the direct costs of an influenza vaccine program be affected by bulk purchase of vaccine?

Medicare Net Costs/Savings of an Influenza Vaccine Program

- What would be the net costs of a Medicare influenza vaccine program?

Congress mandated a study of the cost-effectiveness of a Medicare influenza vaccine benefit but did not specify the measures of cost-effectiveness that would be appropriate for this task. The Department chose to base its recommendations principally on measures of cost-savings to the Medicare program.

The Department defined the cost-savings, or the net costs of a Medicare influenza vaccine benefit, as the sum of:

1. Medicare program expenditures required to pay for vaccinating beneficiaries,

2. Medicare costs of any adverse medical outcomes associated with vaccinations, and

3. Total Medicare payments for influenza-related health care use that would be saved due to increased vaccinations.

The Department implemented the demonstration in 10 sites, each of which included an intervention area (where Medicare provided free vaccine and encouraged the demonstrations to publicize the program) and a comparison area (without free vaccine). The Department bulk-purchased vaccine and distributed it to each site. Providers in the demonstration sites were paid to administer vaccinations. Sites varied in size from paired counties (Monroe and Onondaga Counties in New York) to paired States (Oklahoma and Kansas). Sites were required to develop systems to track and report vaccine usage, to conduct surveillance to monitor the presence of influenza in their areas, and to report the occurrence of adverse medical events linked to vaccinations. In addition to the 10 paired demonstration sites, the Department instructed Medicare Part B carriers in 10 additional States to cover influenza vaccine during the demonstration. The carriers paid providers reasonable charges for the purchase and administration of influenza vaccine.

The Department also funded several studies and data collection efforts to support the demonstration evaluation. Surveys of community-dwelling Medicare beneficiaries and nursing homes were conducted in the demonstration sites to provide annual estimates of vaccination rates. Epidemiological studies using case-control methods were implemented to assess the effectiveness of vaccine in averting hospital admissions. The Department analyzed Medicare claims and eligibility data, at the beneficiary and area levels, in parallel efforts to study vaccine effectiveness and to describe trends in the intervention and comparison areas in influenza-related hospitalizations.

3.0 Implementing and Operating the Demonstration

After an initial year (Federal fiscal year 1989) devoted to start-up activities, during which providers administered only 26,000 doses of demonstration vaccine, the initial nine sites, in Arizona, Massachusetts, Michigan, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, and Texas, began distributing large quantities of vaccine and conducting required tracking and surveillance activities. Illinois, the tenth site, became operational in Year 3 (Federal fiscal year 1991). Table 1 identifies the intervention and comparison areas in each demonstration site.

The Department bulk-purchased and distributed increasing amounts of vaccine to the demonstration sites, from 200,000 doses in Year 1 to 1,328,400 doses in Year 4, at purchase prices that ranged from $0.99 to $1.38 per dose. Total Federal Government expenditures for demonstration administration and influenza vaccine increased as well: $6.2 million (Year 1), $17.2 million (Year 2), $22.1 million (Year 3), and $22.5 million (Year 4). The sites' tracking systems provided a check that reduced misallocations and wastage of vaccine. Claims submitted by providers in the demonstration sites were processed by a single carrier which assisted site staff in acquainting organizations without previous Medicare experience, such as public health departments, about the Medicare claims process. Claims for demonstration vaccine increased from one percent of the total Part B population in Year 1 to 51 percent in Year 4.

The sites recruited providers and encouraged increased vaccination activity among participating physicians, using a variety of motivational techniques. The financial incentives in demonstration payment rates, of $8 per dose for private providers and $4 per dose for public organizations, were emphasized in many sites' recruitment efforts. Direct contact with providers seemed to be more effective than informational mailings. During Year 3,

Medicare Influenza Vaccine Cost-Savings Study
States and Counties Participating
in the Medicare Influenza Vaccine Demonstration

State	Intervention Counties	Comparison Counties
Arizona	Maricopa	Pima
Illinois	Adams, Brown, Bureau, Calhoun, Cass, Christian, Fulton, Greene, Hancock, Henderson, Henry, Knox, Jersey, LaSalle, Logan, Macoupin, Marshall, Mason, McDonough, Menard, Mercer, Montgomery, Morgan, Peoria, Pike, Putnam, Rock Island, Sangamon, Schuyler, Scott, Stark, Tazewell, Warren, Woodford	Alexander, Clark, Clay, Clinton, Coles, Crawford, Cumberland, Douglas, Edgar, Edwards, Effingham, Franklin, Gallatin, Hamilton, Hardin, Jackson, Jasper, Jefferson, Johnson, Lawrence, Marion, Massac, Monroe, Perry, Pope, Pulaski, Randolph, Richland, St. Clair, Saline, Union, Wabash, Washington, Wayne, White, Williamson
Massachusetts	Essex	Worcester
Michigan	Calhoun, Ingham, Jackson, Kalamazoo	Kent, Muskegon, Ottawa
New York	Monroe	Onandaga
North Carolina	Alexander, Burke, Caldwell, Catawba, Cleveland, Durham, Edgecombe, Franklin, Gaston, Johnston, Lee, Lincoln, Mecklenburg, Nash, Orange, Union, Wake, Wilson	Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry, Yadkin
Ohio	Stark, Summit	Franklin
Oklahoma	All Counties	All Counties in Kansas
Pennsylvania	Allegheny	Lackawanna, Luzerne
Texas	Bexar	Bell, Coryell, McLennan, Travis, Yadkin

sites spent from $15 to $18 per participating provider ($0.05 to $0.06 per beneficiary) on these activities.[2]

The sites also implemented community outreach activities, ranging from media publicity to extensive networking through community organizations. Some sites devoted particular attention to minorities and high-risk groups. However, many demonstration site staff agreed that the most effective outreach to beneficiaries was an informational letter mailed by the Department to all beneficiaries in the intervention areas in Years 3 and 4. Outreach expenditures in Year 3, including the informational letter and special site efforts targeted to beneficiaries and providers, totaled $0.33 per beneficiary.

Site performance in surveillance of influenza activity was uneven, and full operation of community-based surveillance was not achieved until Year 3. Most sites discontinued hospital-based surveillance in the face of hospital resistance. However, sufficient surveillance data were collected for Years 2 through 4 to define the weeks during which influenza circulated in each area.

Carriers in four statewide sites (Indiana, Louisiana, Tennessee, and Virginia) were instructed to pay reasonable charges for influenza vaccine beginning in Year 2 of the demonstration. At payment rates ranging from under $6 to $7 per dose, carriers reimbursed providers for 499,565 doses in Year 2, 700,135 doses in Year 3, and 913,883 doses in Year 4. Of the four, only Tennessee implemented an outreach campaign, through an informational letter to all Part B-eligible beneficiaries. In addition to increasing the distribution of vaccine to elderly citizens, the statewide sites, three of which implemented no intensive provider recruitment or beneficiary outreach efforts, provided contrasts to the combined payment and outreach interventions in the 10 demonstration sites. In Year 3,

[2]Year 4 expenditures on provider recruitment and outreach were not available.

the Department added six more statewide sites: Arkansas, Colorado, Idaho, Mississippi, Montana, and Wisconsin which, together, accounted for 579,857 vaccination claims in Year 3, and 793,681 claims in Year 4.

Table 2 reports the number of vaccine claims for all of the paired demonstration and statewide sites, from Year 1 through Year 4 of the demonstration. Overall, among the 20 sites, over 2.7 million doses of vaccine were administered in Year 4.

The Medicare Influenza Vaccine Demonstration proved to be successful at an operational level. It allowed the demonstration sites to plan, develop, and test methods to promote influenza vaccinations and to monitor, develop, or strengthen local influenza surveillance systems. It showed that carriers could quickly implement a program closely resembling a Medicare vaccine benefit including, in one instance, a modest informational effort. It also showed that a system for bulk purchase and distribution of vaccine by the Federal Government was feasible.

4.0 The Effects of Medicare Coverage on Beneficiary Vaccination Rates

The cost-savings potential of Medicare coverage of influenza vaccine hinges not only on the increment in vaccinations resulting from Medicare coverage but also on the underlying vaccination rate among beneficiaries without coverage. Before the demonstration, the 1985 U.S. Immunization Survey provided the accepted estimate of a 22.6 percent vaccination rate for the over-65 population (CDC, 1987). More recent estimates from the 1989 National Health Interview Survey suggested a higher rate of 30.4 percent (Rodgers, 1991). However, because no ongoing national system produces annual data on vaccination rates, the Medicare demonstration conducted surveys of community-dwelling beneficiaries in the 10 demonstration and 4 statewide sites (Indiana, Louisiana, Tennessee, and Virginia) during the study. Annual surveys of nursing homes were also conducted in the 10 demonstration sites.

Table 2

Medicare Influenza Vaccine Cost-Savings Study
Vaccine Claims in the Medicare Influenza Vaccine Demonstration Sites
Year 1 - Year 4

	Vaccine Claims			
	Year 1	Year 2	Year 3	Year 4
Paired Demonstration Sites				
Arizona	7,341	51,855	103,038	132,966
Illinois	NA	NA	73,083	106,573
Massachusetts	1,000	21,025	30,283	40,337
Michigan	334	28,921	45,895	53,572
New York	191	30,980	48,566	56,460
North Carolina	674	49,325	96,913	132,681
Ohio	2,000	50,221	63,662	72,625
Oklahoma	9,618	161,043	207,758	244,539
Pennsylvania	2,100	53,887	74,784	99,399
Texas	2,712	30,059	40,150	56,732
Total	**25,970**	**477,316**	**784,132**	**995,884**
Statewide Sites				
Arkansas	NA	NA	130,736	162,865
Colorado	NA	NA	123,865	141,851
Idaho	NA	NA	44,640	62,783
Indiana	NA	211,052	218,629	267,576
Louisiana	NA	48,588	83,250	117,493
Mississippi	NA	NA	57,162	114,567
Montana	NA	NA	36,452	51,833
Tennessee	NA	133,258	228,705	287,740
Virginia	NA	92,205	136,954	198,517
Wisconsin	NA	NA	187,002	259,782
Railroad Retirement Board*	NA	14,462	32,597	42,557
Total	NA	499,565	1,279,992	1,707,564

Source: Health Care Financing Administration

*Railroad Retirement Board beneficiaries are former members of a railroad employees' health benefits plan which failed and was subsequently subsumed first under Social Security and later under management of the Medicare program.

In the community survey, samples of beneficiaries stratified by age, gender and race were asked whether they had received influenza vaccine in the current and past years, whether they had ever been vaccinated for pneumonia, and whether they were subject to certain high risk conditions (heart disease, asthma, kidney disease, immunosuppression). In the demonstration sites, a combination of telephone, mail, and field interviews achieved completed responses for roughly 500 beneficiaries per area (intervention and comparison), representing response rates of over 90 percent in Years 2 through 4 (a more limited telephone effort achieved a 42 percent response in the demonstration sites during Year 1, and telephone and mail surveys yielded rates over 75 percent in the statewide sites during Years 2 through 4).

After disappointing responses to the nursing home mail survey in Year 1, the demonstration engaged a field interview contractor to survey a sample of 30 nursing homes (with response rates of 75 percent or higher), selected to overrepresent large facilities, in each of the intervention and comparison areas during Years 2 through 4.

Based on data from the community survey, vaccination rates in all intervention areas increased 22 percentage points, from 37 to 59 percent between Year 1 and 4. (Table 3) At the same time, comparison area vaccination rates increased 11 percentage points, from 35 to 46 percent. If trends in the comparison areas represent what would have happened in the intervention areas without the demonstration, then the "vaccination rate effect" of the demonstration would most likely be 11 rather than 22 percentage points.

The contribution to lower Medicare costs of an increase in the vaccination rate depends partly on the risk composition of new vaccinees. If newly-vaccinated beneficiaries are younger, less likely to smoke, or at lower medical risk for complications of influenza than those beneficiaries who regularly received influenza vaccinations before the demonstration, then Medicare might expect to save fewer hospital admissions from increased vaccinations, because low-risk Medicare beneficiaries experience lower pneumonia and influenza (P and I) hospital admissions rates than high-risk beneficiaries and generally have low average vaccination rates.

Table 3

Medicare Influenza Vaccine Cost-Savings Study
Influenza Vaccination Rates: Year 1 - Year 4

	Year 1 (1988-89)*		Year 2 (1989-90)		Year 3 (1990-91)		Year 4 (1991-92)	
	Intervention	Comparison	Intervention	Comparison	Intervention	Comparison	Intervention	Comparison
Paired Sites								
Arizona	39	45	44	50	57	51	59	59
Illinois	30	31	34	33	49	38	53	40
Massachusetts	27	32	29	33	39	41	44	40
Michigan	38	30	40	31	55	41	60	49
New York	49	41	51	46	66	50	70	56
North Carolina	33	31	36	31	47	39	59	40
Ohio	40	31	47	33	52	38	61	42
Oklahoma	42	37	49	39	60	41	67	47
Pennsylvania	38	36	46	38	49	38	52	41
Texas	36	33	41	37	51	44	59	53
Average	37	35	43	38	53	42	59	46
Statewide Sites								
Indiana	35	NA	41	NA	43	NA	46	NA
Louisiana	32	NA	30	NA	35	NA	41	NA
Tennessee	37	NA	40	NA	55	NA	53	NA
Virginia	30	NA	36	NA	42	NA	52	NA

Source: Annual Beneficiary Survey, 1989-1992.

* Year 1 vaccination rate shown here are estimated from responses to the Year 2 survey question, "Did you get a flu shot in the year before last, that is for the winter of 1988 to 1989?" See footnote 11.

During the 4 years of the demonstration, the risk composition of vaccinated beneficiaries in both intervention and comparison areas does not appear to have changed dramatically. From Year 1 to Year 4, the percentage of vaccinated beneficiaries at high medical risk dropped from 59 to 57 percent in the interventions areas and from 60 to 58 percent in the comparison areas. (The average vaccination rate of high-risk beneficiaries remained about 10 percentage points above the rate for low-risk beneficiaries throughout the demonstration.) The percentage of very old beneficiaries among all vaccinated beneficiaries dropped slightly from 8 to 7 percent in interventions areas, and from 10 to 8 percent in comparison areas. Smokers, who were 13 percent of vaccinated beneficiaries in intervention areas in Year 1, were 11 percent in year 4. In comparison areas, smokers declined from 12 to 10 percent. These data suggest that the demonstration had no effect on the risk composition of vaccinated beneficiaries (changes that occurred in risk composition were virtually identical in intervention and comparison areas). Those changes in risk composition that did occur were small and unlikely to have had a significant effect on the P and I hospital admission rate among beneficiaries vaccinated against influenza.

The paired demonstration sites provided evidence on the vaccination rate effect of a program that combines Medicare coverage with outreach to providers and beneficiaries. Evidence on the effects of coverage alone came from the statewide sites. Tennessee, which mailed a purely informational letter to beneficiaries, achieved almost the same increase in vaccination rates achieved by the 10 demonstration intervention areas. Among the other statewide sites, where no attempt was made to inform beneficiaries of the new policy to cover vaccine, vaccination rates only increased by 3 percentage points over the rate of increase in the 10 comparison areas, a reasonable estimate of the effects on vaccination rates of Medicare coverage without outreach.

The nursing home survey found no difference in vaccination rates between intervention and comparison areas; in Year 4, an average of 71 percent of institutionalized

beneficiaries were vaccinated in both areas. Other Federal policies, particularly nursing home regulations in OBRA 1989, combined with pre-existing State and local policies to distribute vaccine to nursing homes, appear to have been more important than the demonstration in determining institutional vaccination policies.

Based on the demonstration data, a Medicare influenza vaccine benefit should raise vaccination rates among eligible community-dwelling beneficiaries by about 3 percentage points, if beneficiaries are not directly informed of the new benefit. If outreach is combined with coverage, the vaccination rate effect should fall within a range from 11 to 22 percentage points. There is no evidence that Medicare coverage would significantly increase vaccination rates among institutionalized Medicare beneficiaries.

5.0 Influenza Vaccine and Medicare-Reimbursable Health Services Utilization

The Effectiveness of Influenza Vaccine

Studies have reported that influenza vaccine is effective in preventing hospitalization and death among the institutionalized and community-dwelling elderly, when the wild virus is Type A (H3N2), closely matched to the vaccine virus, and prevalent at epidemic levels.

A Medicare benefit could not generate savings at any vaccination rate unless the vaccine had a protective effect. As part of the cost-savings study, the Department employed both epidemiological studies based on case-control methodologies and analyses of Medicare claims to test the hypothesis that influenza vaccinations reduce hospital admissions and other health services utilization. The Department also estimated mortality during influenza seasons, using Medicare claims and eligibility records, to support simulations of cost-effectiveness; however, mortality estimates based on claims data alone were not considered to be sufficient to support statistical analyses of vaccine effectiveness in reducing influenza-related deaths.

The Department sponsored three epidemiological studies of vaccine effectiveness: the Michigan and New York studies and the Multisite study.[3] Table 4 presentscomparative estimates of vaccine effectiveness, defined as the percentage reduction in P and I admissions to hospitals due to influenza vaccination. Vaccine effectiveness was estimated for each influenza surveillance season, defined as a 6-month period (November through April) and for influenza circulation periods, when the sites detected circulating virus. For the relatively severe 1989-90 influenza season (Year 2 of the demonstration), the Michigan study estimated that vaccinations reduced pneumonia hospitalizations by 33 percent within a 95 percent confidence interval from 8 to 52 percent. In the milder 1990-91 season (Year 3), the Michigan study estimated an effectiveness rate of 17 percent (within a 95 percent confidence interval from 0 to 35 percent). The Multisite study also reported results for Year 3. This study found no protective effect of the vaccine, after adjustment for risk factors that might have confounded estimates of vaccine effectiveness. In 1991-92 (Year 4), the Multisite study found vaccine to be 33 percent effective based on comparisons among hospital patients. The Michigan and Multisite studies reported nonsignificant effectiveness estimates below 20 percent when P and I patients were compared to individuals in the community. New York investigators found statistically significant evidence for effectiveness only in Year 3. Findings based on data from well-defined influenza circulation periods suggested somewhat higher rates of vaccine effectiveness.[4]

[3]The Michigan study, conducted in Years 2, 3, and 4 of the demonstration, and the Multisite study, conducted during Years 3 and 4 in Ohio and Pennsylvania, compared the influenza vaccination histories of hospitalized pneumonia cases to those of pneumonia-free controls, to determine whether or not the proportions vaccinated in the two groups differed. The New York study, conducted in Years 2 through 4, compared vaccination histories between pneumonia patients with and without evidence of antecedent influenza infection.

[4]Research in the epidemiological studies also suggested that pneumococcal vaccine protects against P and I hospital admissions. Additional information on the separate and combined effects of influenza and pneumococcal vaccine will be included in the final report of the study (October, 1993).

Table 4

Medicare Influenza Vaccine Cost-Savings Study

Summary of Influenza Vaccine Effectiveness Estimates According to Influenza Season and Case-Control Study

	1989-90 Year 2	1990-91 Year 3	1991-92 Year 4
Influenza Season Characteristics			
Excess P&I Mortality	Yes	No	Yes
Predominant Type	Flu A/H3N2	Flu B	Flu A/H3N2
Circulation Period	Dec. - Feb.	Jan. - Apr.	Nov. - Feb.
Vaccine Match	Excellent	Excellent	Excellent
Vaccine Effectiveness Over Entire Influenza Surveillance Season			
Michigan Study[1]			
Community Comparison	33%* [8,52][4]	17% [0,35]	11% [-9,28]
Multisite Study[2]			
Community Comparison	--	-73%[5]* [-141,-23]	17% [-9,37]
Hospital Comparison	--	-2% [-38,25]	33%* [11,49]
New York Study[3]			
Hospital Comparison	17% [-43,51]	41%* [1,65]	12% [-34,42]
Vaccine Effectiveness During Defined Influenza Circulation Periods			
Michigan Study			
Community Comparison	45%* [14,64]	31%* [4,51]	32%* [7,50]
Multisite Study			
Community Comparison	--	--	33%* [5,53]
Hospital Comparison	--	--	41%* [15,60]
New York Study			
Hospital Comparison	36%	--	46%

* Logistic regression estimates attaining statistical significance at $p \leq 0.05$.

n.b. The New York Study population incouded nursing home patients, hence estimates are not entirely representative of the general Medicare population.

[1] Southern Lower Michigan

[2] Allegheny County, PA; Franklin and Summit Counties, OH

[3] Rochester County, NY

[4] Confidence intervals are presented in parentheses.

[5] Since it is biologically impossible for influenza vaccine to cause pneumonia, this estimate is most likely confounded by high-risk conditions in the cases which increase the likelihood of both influenza vaccination and pneumonia hospitalization.

A second analysis of vaccine effectiveness linked information on beneficiaries' vaccination status, from the community vaccination surveys and from demonstration vaccine claims, with Medicare claims for reimbursable hospital inpatient services incurred during the influenza seasons in Years 2, 3, and 4 to compare rates of Medicare-reimbursed health services utilization between vaccinated and unvaccinated beneficiaries. Generally speaking, beneficiaries suspected to be at high risk for influenza-related complications were both more likely to be vaccinated and were from two to five times more likely to be hospitalized during the influenza season than low risk beneficiaries, complicating the detection of a protective effect of the vaccine. However, even after adjusting for risk status and other factors, no statistically significant differences were detected in inpatient admissions and reimbursements (for P and I admissions associated with influenza).[5]

Similar analyses suggested a link between the vaccination status of high-risk elderly beneficiaries and admission to a skilled nursing facility (SNF) during the peak periods of two severe influenza seasons (Years 2 and 4 of the demonstration). In Year 2, the probability of a Medicare-covered SNF admission for unvaccinated beneficiaries was 0.0031, compared to 0.0010 for vaccinated beneficiaries. Corresponding rates in Year 4 were 0.0052 and 0.0027. However, differences were not statistically significant at conventional levels (0.08 in Year 2 and 0.09 in Year 4). In Years 1 and 3, no differences were detected. Similar comparisons over a broader period in each of the four demonstration years (from November through April) showed no statistically significant differences. The Department determined that, although evidence suggests some protective effect of influenza vaccine against SNF admissions among the high-risk elderly, the data do not warrant an unambiguous conclusion at this time.

[5]P and I admissions include International Classification of Diseases, 9th revision (ICD-9), codes 480-487 (Diagnosis Related Groups (DRG) 79, 80, 89, and 90).

Although the sum of these findings calls into question earlier optimistic reports that the vaccine confers substantial protection against influenza-related morbidity, evidence from the epidemiological studies suggests that vaccine may have been effective in severe influenza seasons (Year 2) in certain areas (sites in Michigan, New York, Ohio and Pennsylvania) where the season's vaccine matched the circulating virus, and where the circulating virus was particularly threatening for elderly persons. Based on confidence intervals around estimates from each year's influenza season (November through April), effectiveness of the vaccine is assumed to vary from zero to 35 percent in mild years and from zero to 52 percent in severe years.

Medicare Coverage and P and I Hospital Admissions Rates

In a final series of tests, trends in population rates of P and I hospital admissions (during November through April of each demonstration year) were contrasted between intervention and comparison areas. Unlike the previously discussed estimates of vaccine effectiveness, these tests searched for the combined effects on elderly P and I hospital admissions rates of 1) Medicare coverage and outreach on vaccination rates (the vaccination rate effect) and 2) vaccine effectiveness, the protective effect of vaccine that deters hospital admissions. At any level of vaccine effectiveness, P and I hospital admissions rates should have been lower than expected in areas where vaccination rates were higher than expected. Evidence of reduced hospital admissions rates should have appeared late in the demonstration, when sites had distributed large quantities of vaccine, and in sites that experienced 1) the largest increases in intervention area vaccination rates (above baseline) and 2) the largest differentials in vaccination rate increases between intervention and comparison areas.

Several methods for detecting effects were tried:

1. contrasts of average P and I admissions rates in all intervention areas with all comparison areas, in each season and over time, with and without adjustment for other factors that might explain P and I admissions rates;

2. similar contrasts involving a subset of intervention areas with above-average performance in achieving vaccination rate increases; and

3. contrasts of intervention areas with alternative comparison areas, selected according to similarity in P and I admissions rates during months when influenza did not circulate.

Parallel tests were conducted during influenza and non-influenza periods to determine whether or not observed differences between intervention and comparison areas persisted throughout the year.

Reductions in admissions rates were expected to be small and difficult to detect (from 1 to 3 percent), given the many factors than contribute to the differences in hospital admissions rates. Statistical power was sufficient to detect small reductions, once estimates were adjusted for some of these other factors. However, interpreting these reductions as "effects" of the demonstration proved to be problematic.

For the most part, although some tests yielded statistically significant differences in the appropriate direction (intervention area P and I admissions rates below comparison area rates during influenza seasons), equally-significant differences during non-influenza periods suggested that factors other than vaccination rates explained admissions rate differentials. The Department concluded that area-level data could not demonstrate any reductions of P and I hospital admissions rates associated with Medicare coverage of influenza vaccine.

6.0 The Direct Costs of a Medicare Influenza Vaccine Benefit

Total expenditures for a Medicare influenza vaccine benefit program would include Medicare's share of the costs of production, distribution, and administration of the vaccine; costs of program management (program publicity, tracking vaccine usage, claims processing, general management); and the indirect costs incurred to treat adverse medical

events associated with influenza vaccination. HCFA estimated total costs per beneficiary for alternative program models:

- a traditional system (with and without government efforts to publicize the program) similar to the pneumococcal vaccine model, in which Medicare pays providers 100 percent of reasonable charges for vaccinating beneficiaries and providers purchase the vaccine directly from distributors or manufacturers;

- a bulk-purchase system, in which CDC buys and distributes vaccine under the benefit and Medicare pays providers only the cost of administering the bulk-purchased vaccine.

Cost estimates were generated for programs with and without the level of outreach effort expended by the sites during the demonstration: programs without outreach were assumed to achieve lower vaccination rate increases (estimated to be about 3 percentage points, based on experience in Indiana, Louisiana, and Virginia) than programs with outreach (11 to 22 percentage points, based on experience in the 10 demonstration sites and Tennessee). For the bulk purchase system, quantity discounts on purchase prices were computed using data from the demonstration. Other cost elements were computed from information collected through reviews of the trade literature and conversations with manufacturers, distributors and other knowledgeable individuals.

The Department computed program costs per vaccinated beneficiary under a traditional purchase and distribution model as the sum of:

- Manufacturers' price. Communications with manufacturers established an average manufacturers' price per dose of $2.00, with an estimated 35 percent markup for distribution, for a total retail price of $2.70. Carriers in the statewide sites paid an average reasonable charge of $4.57 per dose during the demonstration. The Department chose to use $2.70, on the assumption that carriers under a national program would adjust payments down to market rates (although this clearly did not happen during the demonstration).

- Vaccine administration. Carriers paid an average of $2.15 per dose to cover provider vaccine administration. Lacking alternative estimates, the Department used this figure in computing program costs.

- Other program costs. The Department added the following components to compute total program costs: 1) claims processing costs, estimated at $0.72 per claim, based on carrier experience during the demonstration; 2) costs of adverse medical events associated with vaccination -- assuming that 5 percent of adult vaccinees experience adverse events (OTA, 1981), and 1 percent of these visit a physician, at $23.24 per "limited office visit" (based on 1991 Part B payment rates), costs were estimated to be $0.01 per dose when the vaccination rate is 40 percent; and 3) carrier informational letter, based on demonstration data, estimated to be $0.50 per dose when the vaccination rate is 40 percent.

At a 40 percent vaccination rate, program costs in a traditional system with an information letter would be $6.08 per dose ($2.43 per beneficiary, for all eligible community-dwelling and institutionalized elderly individuals).[6] Of this total, $4.85 per dose represents the costs of buying, distributing and administering the vaccine.

Estimates of bulk-purchase program prices differed from the traditional model in the following two ways: 1) purchase prices were discounted as the volume of vaccine acquired by the government increased, reflecting the discounts that the government achieved during the demonstration; and 2) certain administrative costs, including costs of tracking vaccine utilization and negotiating purchase contracts, were added into total program costs.

Of all program models, the centralized bulk-purchase system generates the lowest cost per beneficiary. Assuming a vaccination rate effect of Medicare coverage (without the carrier letter) equal to 10 percentage points above the baseline rate (40 percent vaccination rate), the centralized bulk-purchase system costs $5.08 per dose ($2.03 per

[6]As noted earlier, the demonstration had no measurable effects on vaccination rates or vaccination policies in nursing homes. However, if Medicare introduces an influenza vaccine benefit, it will be liable for all of the costs of vaccinating eligible beneficiaries in nursing homes. On average, 5 percent of the elderly are in a nursing home in any year (U.S. Department of Commerce, 1992). If the average nursing home vaccinates 70 percent of its eligible elderly residents, then the "true" vaccination rate for all institutionalized and non-institutionalized elderly will be slightly higher than the rate for community-dwelling elderly (for example, 41.5 percent, when the community-dwelling rate is 40 percent).

beneficiary), compared to $5.58 per dose ($2.23 per beneficiary) for the traditional system. With an outreach program in place, the costs of a centralized system rise to $2.23, compared to $2.43 for the traditional system ($5.58 and $6.08 per dose, respectively). The cost advantage of bulk-purchase increases with higher vaccination rates. Assuming no expenditures for outreach, the cost per beneficiary in a traditional system is 10 percent higher than the bulk-purchase cost for a 10 percentage point vaccination rate increase and 17 percent higher for a 20 percentage point increase.

Of course, from Medicare's perspective, the relative advantages of alternative program models depend both on program costs and on the off-setting reductions in Medicare reimbursements achieved if the vaccine is effective.

7.0 The Cost-Savings and Cost-Effectiveness of a Medicare Influenza Vaccine Benefit

The Medicare Influenza Vaccine Demonstration showed that Medicare coverage, with some publicity about the availability of subsidized vaccine, would effect a change in vaccination behavior among the community-dwelling elderly but not among elderly residents of nursing homes. However, despite evidence that payment incentives work to increase vaccination rates and that studies conducted in conjunction with the demonstration provide some evidence that vaccinations reduce hospital admissions rates or total Medicare-reimbursed expenditures for the consequences of influenza, the Department incorporated both pessimistic and optimistic estimates of vaccine effectiveness in simulations of the expected cost-savings from an influenza vaccine benefit.

Cost-Savings Estimates

The Department estimated measures of cost-savings (vaccination program expenditures minus offsetting reductions in influenza-related health services expenditures). Cost-savings for the Medicare program counts as savings only those reduced Medicare-reimbursed expenditures generated by increasing vaccination rates above the baseline rate. Measures of vaccine effectiveness were averaged over severe and mild influenza seasons,

to capture the implications for cost-savings of funding a program that is bound to vary across time in its potential for savings, regardless of how effective the vaccine proves to be in any single season. The Department used the following formula to calculate cost savings:

Total Medicare Net Costs = Vaccine Program Costs
- Savings in Hospital Payments (10-Year Annual Average)

Vaccine Program Costs: Includes costs of buying, distributing, and administering the vaccine; administering a Medicare vaccination program (claims processing, general administration); and costs of outreach to beneficiaries and providers (in some models).

Savings in Hospital Payments: An average, that accounts for different hospitalization rates and different rates of effectiveness in years with severe influenza seasons and mild influenza seasons over the past decade.

Savings (Single Year) = R * H * E * [V(b) - V(0)]

R = Medicare payments per P and I hospital admission (estimated to be $5,308 in 1991, for admissions with ICD-9 codes 480-487 in any position on the Medicare claim -- equivalent to DRGs 79, 80, 89, 90 -- includes DRG payments plus adjustments for passthrough payments to hospitals under Perspective Payment Systems, and includes a 20 percent inflation factor to incorporate Part B reimbursable services delivered during the hospital stay.)[7,8]

[7]The estimate of 20 percent is based on an "inpatient condition package for pneumonia DRGs," in Mitchell et al. (1983), which includes Part B-reimbursable professional services associated with a hospital admission in DRGs 89 and 90. In 1981, the total, which was $322, was 15 percent of total Medicare Part A reimbursement for a P and I hospital admission. This figure was inflated to 20 percent to allow for increased Part B billing due to practice pattern changes since 1981.

[8]The Department, on the basis of findings from analyses of Medicare claims, included no estimates of savings from reduced skilled nursing facility admissions.

H = P and I hospital admissions per aged Part B eligible beneficiary. Separate rates were calculated for severe and mild years. Severe year rate = .01613, and mild year rate = .01497.[9]

E = vaccine effectiveness, ranging from 5 to 70 percent -- includes the range of effectiveness estimates generated in the case-control studies associated with the demonstration.

V(b)= the vaccine rate under the benefit, ranging from 35 to 60 percent, and V(0), a baseline vaccination rate (30 percent) -- includes the estimated effects on elderly vaccination rates of Medicare coverage on vaccination rates (more than zero and less than 30 percentage points), based on demonstration data.

Savings (10-Year Annual Average) = .4*Savings-Severe Year + .6* Savings-Mild Year (assumes severe epidemic in 4 of 10 years)

Table 5 illustrates how a representative estimate of net costs was calculated, assuming a vaccination rate of 40 percent (a "vaccination rate effect" of 10 percentage points above baseline), vaccine effectiveness of 40 percent in severe years and 20 percent in mild years, and a traditional Medicare purchase and distribution system with minimal outreach to beneficiaries (a carrier informational letter). Estimates of vaccine program costs are shown in the left column, totaling $2.43 per beneficiary ($6.08 per dose). Separate estimates of savings for severe and mild years are calculated in the two right-hand columns, each of which represents the formula for single year savings presented above. Weighting these estimates by .40 and .60 respectively and summing produces

[9]Severe season rate = 503,415 P and I admissions from November 1991 through April 1992, divided by 31,210,800 aged Part B-eligible Medicare beneficiaries (1991). Mild season rate = 459,658 admissions from November 1990 through April 1991, divided by 30,699,500 aged Part B-eligible Medicare beneficiaries (1990). Disabled Medicare beneficiaries under age 65 were not included in these analyses. The Department recognizes that all Part B-eligible beneficiaries will have access to the benefit. However, most research used to support this study focuses on the elderly, and findings from this research probably would not apply to the small number of younger disabled beneficiaries who would be considered at sufficient medical risk under ACIP guidelines to need influenza vaccinations.

Table 5

Medicare Influenza Vaccine Cost-Savings Study
Estimate of Net Medicare Costs for Table 6

EFFECTIVENESS: Severe Season (.40), Mild Season (.20)
VACCINATION RATE: .40

Cost/Beneficiary		Savings/Beneficiary	Severe Year	Mild Year	
Vaccine	$0.80	Cost/P&I Hospital Admissions	$5,308	$5,308	
+ Administration and Claims Processing	1.15	x P&I Hospital Admissions (per beneficiary)	.01613	.01497	
+ Distribution	0.28	x Effectiveness Rate	.40	.20	
+ Outreach	0.20	x Vaccination Rate Effect	.10[1]	.10[1]	
+ Adverse Medical Outcomes	Less than 0.01	x Probability of Severe/Mild Season	.40	.60	
VACCINE PROGRAM COSTS/BENEFICIARY =	$2.43	TOTAL SAVINGS IN HOSPITAL PAYMENTS (TEN-YEAR ANNUAL AVERAGE)/ BENEFICIARY) =	$1.37 +	$0.95 =	$2.32

TOTAL NET MEDICARE COST/BENEFICIARY: $2.43 - $2.32 = $0.11

(TOTAL SAVINGS/TOTAL COST) x 100 = 95 percent

TOTAL NET COST TO THE MEDICARE PROGRAM ≈ $3.4 million*

*31 million eligible aged beneficiaries.

10-year annual average savings in hospital payments per beneficiary of $2.32. Total net Medicare costs per beneficiary are $0.11 ($2.43 - $2.32). Savings represent 95 percent of costs. This estimate implies that, for an aged beneficiary population of about 31 million, Medicare would increase total expenditures by $3.4 million to extend coverage for influenza vaccinations. This representative estimate appears as one in a range of similar estimates in Table 6.

Under assumptions supported by data from the demonstration, there is no conclusive evidence that a vaccine benefit would either increase or reduce Medicare costs. Table 6 presents estimates of the average annual net costs per beneficiary of a vaccine benefit program. Row one shows the cost to the Medicare program of vaccinating the baseline Medicare population who pay for their own vaccinations. The Medicare program already benefits from reduced admissions because of these vaccinations. Rows two through five show savings offset by the added Medicare costs of a vaccine benefit. Program costs are generated by a purchase and distribution system similar to the present Medicare pneumococcal vaccine program plus a regular yearly informational letter on the benefit from each Medicare carrier to each eligible beneficiary.

Among the 32 estimates of net expenditure at vaccination rates of 35 percent and higher shown in Table 6, 19 represent added costs for Medicare and 13 represent savings. At a 40 percent vaccination rate (representing a 10 percentage point increase over the baseline, close to the minimum "vaccination rate effect" of coverage and outreach in the demonstration), and vaccine effectiveness rates of 40 and 20 percent in severe and mild years respectively (at the high end of a range of estimates in the case-control studies), Medicare would incur added costs per beneficiary of $0.11, or about $3.4 million. At vaccine effectiveness rates of 42 and 21 percent, the "break-even" effectiveness rates when the vaccination rate is 40 percent would be "budget neutral," implying zero net costs. At vaccine effectiveness rates of 50 and 25 percent, a Medicare vaccine benefit would generate net savings of $0.47 per beneficiary, or $14.6 million.

Table 6

Medicare Influenza Vaccine Cost-Savings Study
Net Medicare Expenditures Per Beneficiary[1]
Traditional Medicare Purchase and Distribution System

Vaccination Rate	Vaccine Effectiveness (Percentage Reduction in P&I Hospitalization Rate) (Severe Year)[2] .05	.10	.20	.30	.40	.50	.60	.70	Budget-Neutral Vaccine Effectiveness Rates[4] (Severe Year)[2]
.30 (Baseline)[3]	$1.88	$1.88	$1.88	$1.88	$1.88	$1.88	$1.88	$1.88	-
.35	$2.01	$1.86	$1.57	$1.28	$0.99	$0.70	$0.41	$0.12	.74
.40	$2.14	$1.85	$1.27	$0.69	$0.11	($0.47)	($1.05)	($1.63)	.42
.50	$2.41	$1.83	$0.67	($0.49)	($1.65)	($2.82)	($3.98)	($5.14)	.26
.60	$2.68	$1.81	$0.07	($1.68)	($3.42)	($5.16)	($6.90)	($8.65)	.20

Source: Medicare Influenza Vaccine Demonstration Data; Medicare Claims

[1] Total program expenditure minus total estimated savings in Medicare P&I hospital reimbursements based on increases over the baseline vaccination rate. Savings includes Medicare Part A hospital payments plus 20 percent, to simulate Medicare Part B (physician and other) payments for services provided in the hospital. Negative numbers (net savings) in parentheses.

[2] Vaccine effectiveness rate in mild influenza years is one-half the rate assumed for severe influenza seasons. Mild seasons are expected to occur during 6 out of 10 years.

[3] Baseline Row: Cost to the Medicare program of vaccinating the 30 percent of the Medicare population who pay for their own vaccinations.

[4] Vaccine effectiveness rates at which, for a given vaccination rate, the program is budget-neutral (zero net expenditures).

The assumptions used to produce these findings were changed in sensitivity tests.[10]

- First, program design was varied to allow for centralized purchasing. If the Federal Government were to bulk-purchase influenza vaccine under a new benefit program, net savings (or costs) would be increased (or reduced) a few cents per beneficiary. For example, in the base case presented in Table 6, assuming 40 percent vaccination and 40 percent effectiveness, bulk purchase would generate net costs of $0.04 per beneficiary, compared to a net cost of $0.11 per beneficiary under a traditional system.

- Two extreme assumptions about vaccine effectiveness in severe and mild years were tested: one case assumed vaccine was equally effective in all years, and the other assumed vaccine was totally ineffective in mild seasons. Net costs are clearly sensitive to assumptions about changes in the effectiveness of the vaccine from year to year. For example, assuming a 40 percent vaccination rate and a 40 percent rate of vaccine effectiveness in all years, the model yields savings of $0.57 per beneficiary. However, for these same assumption, the model in which vaccine is 40 percent effective in severe years and totally ineffective in mild years yields net costs of $1.06 per beneficiary.

Total estimated costs and savings clearly change under alternative assumptions, but the Department's overall conclusion, that the demonstration provided no clear and unambiguous finding for or against cost-savings, does not change.

Cost-Effectiveness: Reductions in Mortality and Other Implications of a Medicare Benefit

The Department also estimated the net costs per death averted and per year of life saved of implementing a Medicare influenza vaccine benefit. Findings show that influenza vaccine would compare favorably with other preventive services now covered.

[10]McBean et al. (1993) have shown that influenza may impact on other causes of hospitalization in the elderly Medicare population. In addition to hospitalizations where P and I was diagnosed as either principal or other cause of admission, hospitalizations for acute bronchitis, chronic respiratory disease and congestive heart failure increased during the influenza season. If these outcomes were included, the net cost of the benefit would be reduced.

Pneumonia and influenza deaths were estimated by counting all deaths among aged Medicare beneficiaries within 30 days of a P and I hospital admission occurring during the period from November through April. Two estimates were used: a severe year estimate, based on Year 4 of the demonstration (28.38 deaths per 1,000 beneficiaries) and a mild year estimate, based on Year 3 (25.83 deaths per 1,000 beneficiaries). Life expectancy in 1989 for individuals over 65 was estimated to be 12.69 years (National Center for Health Statistics, Vital Statistics of the United States, 1992).

If it is assumed that vaccine is 40 percent effective both at reducing hospital admissions and at averting deaths, and that the vaccination rate among Medicare beneficiaries is 40 percent, then the case presented in Table 6 yields a cost per death averted of $1,871. By this measure, influenza is clearly more cost-effective than breast cancer screening, which Moskowitz (1987) estimated to cost $123,000 to avert a single death.

Using the same assumptions, influenza vaccine would cost $145 per year of life saved, well below costs for other preventive interventions. The OTA (1979) estimated that pneumococcal vaccine would cost about $1,000 per quality adjusted life year (a slightly different measure of added years of life that adjusts for disability days). Mandelblatt (1988) estimated the cost of an added year of life gained through cervical cancer screening to be $1,600 to $2,900.

Several effects of an influenza vaccination program that were not quantified in this analysis should be noted. In addition to the financial implications for Medicare and mortality effects, influenza vaccinations can be expected to have beneficial effects on individuals' quality of life, by alleviating anxieties about illness and reducing the pain and suffering of influenza and its aftermath. Any savings in Medicare expenditures will be accompanied by savings in copayment expenditures of other third party payers and out-of-pocket payments by beneficiaries. Working elderly should gain financially from reduced

work-loss, and society will presumably benefit from higher productivity of the elderly work force. Reductions in influenza-related illness due to increased vaccinations could also have indirect productivity effects by preserving the working hours of employed relatives or friends who might be called on to care for ill elderly individuals.

Conclusion

The Medicare Influenza Vaccination Demonstration proved that coverage of influenza vaccinations, with some outreach to beneficiaries and providers, would increase vaccination rates among the elderly. Findings on the effectiveness of the vaccine during the demonstration were mixed. Estimates of Medicare's net costs based on these findings did not conclusively demonstrate that the benefit would add or save Medicare expenditures. However, influenza vaccine appears to be cost-effective, in deterring deaths associated with influenza, compared to other preventive services currently covered by Medicare.

The OBRA 1987 legislation provided for automatic implementation of a Medicare influenza vaccine benefit unless the Department were to conclude that the benefit would not be cost-effective. It is not possible to reach such a definitive negative conclusion. In order to find that the benefit would not be cost-effective, incapable of generating net savings in Medicare expenditures, the Department would have to show no net savings under most reasonable assumptions about the effects of coverage on vaccination rates and about the effectiveness of influenza vaccine in reducing Medicare expenditures.[11] The range of "reasonable" assumptions is a broad one, based on studies completed as part of this demonstration and on research reported in the literature.

[11] Although the Department used cost-savings for the Medicare program as the primary criterion for evaluating a new benefit, estimates of cost-effectiveness (net costs per death averted, per year of life saved) provide further support against a definitive negative conclusion. Cost-effectiveness studies of other preventive services covered by Medicare report estimates that differ widely, for a variety of reasons. The most generous estimates (for mammography, for example) exceed the largest reasonable estimate of the costs per death averted by an influenza vaccine program by thousands of dollars.

As this report shows, statistical estimates of the effectiveness of influenza vaccinations vary greatly in size among influenza seasons, across geographical areas, and among research studies. These measures are also subject to large estimation errors within seasons and areas. This variation reflects the wide fluctuations in the nature and severity of influenza and the considerable difficulties investigators encounter when trying to identify events, such as hospital admissions and deaths, that are caused by influenza.

In addition, although the findings from annual surveys convincingly demonstrate that Medicare coverage can increase the vaccination rate (particularly when accompanied by some informational outreach to beneficiaries), maximum and minimum estimates of Medicare coverage effects on vaccination rates differ by nearly a factor of 4.

Within the constraints set in the legislation, and based on data from the demonstration, the Department concludes that the cost-saving potential of a Medicare influenza benefit is ambiguous. Therefore, Medicare will initiate coverage for influenza vaccinations at the beginning of the first month after the date of this report.

The Department believes that the new benefit could generate effects on the Medicare program within a wide range, from added costs (roughly $57.7 million at 10 percent vaccine effectiveness and a 35 percent vaccination rate) to significant savings ($51.2 million at 40 percent vaccine effectiveness and a 50 percent vaccination rate). Within this range, the evaluation contractor estimated that an added expenditure of $21.4 million (30 percent vaccine effectiveness and a 40 percent vaccination rate) appears to be most consistent with findings from the demonstration. HCFA's Office of the Actuary estimated projected costs as follows: $50 million in fiscal years (FY) 1994 and 1995; $45 million in FYs 1996 and 1997; and $40 million in FY 1998.

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